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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO.       |
|---|-------------|----------------------|--------------------------------|------------------------|
| 10/501,682  | 02/02/2005  | Paul G Shiels        | 0380-P03437US0                 | 4505                   |
| 110 7590 11/05/2007<br>DANN, DORFMAN, HERRELL & SKILLMAN<br>1601 MARKET STREET<br>SUITE 2400<br>PHILADELPHIA, PA 19103-2307 |             |                      | EXAMINER<br>MONTANARI, DAVID A |                        |
|   |             |                      | ART UNIT<br>1632               | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>11/05/2007        | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/501,682 | <b>Applicant(s)</b><br>SHIELDS, PAUL G |  |
|                              | <b>Examiner</b><br>David Montanari   | <b>Art Unit</b><br>1632                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-17, 20-22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 11-17, 20-22, 24-27 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 28, 29, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/9/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Applicants amendments filed on 8/9/2007 have been entered.
2. Claims 1, 7, 8, 31 and 32 have been amended.
3. Claims 10, 18, 19 and 33-35 have been cancelled.
4. The rejection of claim 7 under 35 USC 112, first parag. written desc., is withdrawn.
5. The rejection of claim 9 under 35 USC 112, second parag. is withdrawn.
6. Claims 1-4, 7-9, 28, 29, 31 and 32 are examined in the instant application.

### ***Objections***

Applicants has amended claim 1 to recite that G22P1 protein is examined in the donor tissue. Claim 31, which depends from claim 4 and further depends from claim 1 recites that the method further comprises determining the expression level of other proteins to include G22P1, which does not further limit the claim. This appears to be a typo as Applicant has deleted G22P1 in claim 7 for example.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7-9, 28-29, and 31-32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record in the office action mailed on 2/9/2007.

***Response to Arguments***

Applicant argues in amendment filed on 8/9/2007 that in view of *In re Wands*, the claimed method does not require an undue amount of experimentation when viewed by the skill of the ordinary artisan. Specifically Applicant argues that the skilled person frequently assesses factors including gene expression levels when tissue is to be considered for transplantation. Applicant continues that several non-patent literature has been submitted with their response to support the position that analyzing gene expression levels in renal grafts is routine. Applicant argues that claim 1 has been amended to recite that the reference level of expression is that observed in a healthy tissue sample. Applicant continues that Melk et al. does show that it is possible to correlate telomere length to renal tissue with age and that Joosten et al. make no mention of G22P1. These arguments are not persuasive.

While Applicant has amended the claimed method to now recite a specific endogenous telomere binding protein, G22P1, and that the reference level of expression is now observed in a healthy tissue sample, significant issues remain regarding the enablement of the claimed method. First there is no limitation in the claimed method that the donor tissue and the healthy tissue sample now recited be of the same tissue type. The donor tissue could be heart and the healthy tissue sample could be kidney. See pg. 6 of the previous non-final rejection for discussions on this matter. This contrast would make the claimed method highly unpredictable for the skilled artisan to practice. One could argue that it would be obvious to use the same tissue types for both the donor and the healthy tissue sample, but given the broadest reasonable interpretation of the

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claimed method, two different tissue types are being contrasted with respect to G22P1 expression levels. Secondly, Applicants arguments and the references supplied do not address the issues still remaining with respect to a reference level of G22P1 expression levels in a healthy tissue sample. The art of record teaches that telomere binding protein levels are transient with age and that determining a reference level would be significantly difficult for the skilled artisan. Simply put, there is no reference level for G22P1 protein expression in any tissue. For example, the levels of G22P1 protein would be different in a 6-year old renal sample vs. a 45-year old renal sample. The art of record does not address G22P1 expression levels with respect to transplantation but that telomere binding proteins, of which G22P1 belongs to, are transient and not predictable. Thus for reasons of record and above the rejection is maintained.

No claims are allowed.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108.

The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.

  
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